

UPDATE BRIEFING PAPER # 6

OP Pilot Public Participation Process

The following paper provides a review of phases 4 and 5 of the OP Pilot Public Participation Process, and is accompanied by several summary attachments. The first attachment (6-A) is a text box that provides an overview of each of the 6 phases in the OP Pilot Public Participation Process. The second attachment (6-B) is a flow diagram and gives an overview of process phases 4 - 6. Recognizing different preferences for how information is presented, Attachment 6-C provides the same information as Attachment 6-B but in bar diagram form. In addition, TRAC Staff Paper # 34 (9/9/98) is attached for reference purposes.

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Introduction.

EPA and USDA are now using a pilot process for involving the public in the reassessment of tolerances (FQPA) and reregistration (FIFRA) of individual organophosphate (OP) pesticides. The pilot process was developed as part of the Tolerance Reassessment Advisory Committee (TRAC) to find a more effective way for the public to participate at critical junctures in the Agency's development of OP risk assessment and risk management decisions. EPA and USDA began implementing this pilot process in August 1998 to increase transparency and opportunities for stakeholder consultation (see TRAC Staff Papers #27 and #34).

Overview of the Pilot Process.

The pilot process consists of several phases, starting with the first opportunity for external comment where the registrant of the OP is given a 30-day opportunity to identify errors in the preliminary human health and ecological risk assessment(s) (Phase 1). After the registrant's comments on errors are considered (Phase 2), the preliminary risk assessment and related documents are released to public (Public Docket and EPA's Internet website) for a 60-day review and comment period. All interested parties are invited to comment (Phase 3). During Phase 4, EPA considers public comments and refines the risk assessment, considering any input from USDA. Subsequent phases involve the public in the development of risk management and transition options.

Status of the Pilot Process.

EPA has made good progress in releasing assessments to the public since the initiation of the pilot public participation process in August 1998. As of February 24, 1999, 30 OPs have started the pilot process, of which preliminary risk assessments for 28 OPs have reached Phase 3 at a minimum (i.e., the assessments have been placed in OPP's Public Docket and Internet website for review and comment). The status of OPs currently in the pilot process are as follows:

- **Phase 2** – 2 OPs – Registrant error correction comments on preliminary risk assessments are now being considered.
- **Phase 3** – 13 OPs – Preliminary risk assessments are available for public comment.
- **Phase 4** – 15 OPs – Refined risk assessments are being developed.

Phase 4. Development of Refined Risk Assessment Documents.

- Overview of Phase 4. This phase begins at the close of the 60-day public comment period (Phase 3), where the public has an opportunity to review and submit comments on the preliminary risk assessments and other materials that have been placed in OPP's Public Docket (and EPA's Internet website). Refined risk assessments are developed and sent to USDA for intergovernmental review, after which public meeting(s) ("Technical Briefings") may be held to provide interested stakeholders with further opportunities to gain insight into the refined risk assessments (including which uses are the major contributors ["drivers"] of risk). Below are the 3 steps that occur during Phase 4.
- Development of refined risk assessment documents. EPA considers public comments on preliminary risk assessments and develops the refined risk assessment. An Overview is prepared that summarizes the risk findings, including the endpoints that were used, the "risk drivers" (e.g., the major risk contributors and other factors that impact the assessment of risk), and use data that were used in developing the assessment. A short Summary document, similar to a Fact Sheet, is also prepared highlighting the major points.
- Intergovernmental Review -- Transmission to USDA. EPA transmits to USDA the refined risk assessment, Overview, and Summary documents for their review, and provides briefings for the USDA review team at anytime during their review. USDA will focus their review on the risk assessment's utilization of use and usage information/data, assumptions used in the assessment, and on possible strategies/options for managing risk. USDA may draw on their employees in the Cooperative Extension System (Land Grant Universities) to review areas/topics in the refined risk assessments that are germane to their area of expertise (it is understood that the documents will not be released to non-USDA employees). USDA will transmit their comments to EPA, and EPA and USDA will work together to consider and incorporate their comments into the refined risk assessment, Overview, and Summary.

The Department of Health and Human Services (DHHS) will serve a role similar to USDA for all public health uses of OPs. Other federal government agencies also may be considered depending on the particular situation.

- Technical Briefing. EPA and USDA usually will hold a public meeting -- called a Technical Briefing -- on the refined risk assessment. The Technical Briefing is designed to provide interested stakeholders with an opportunity to become even more informed about an OP's risk assessment. EPA will describe in detail the refined risk assessment, including the major points laid out in the Overview (e.g. risk contributors and drivers), how public comment affected the assessment, and the use information/data that were used (e.g. PDP data). USDA will provide ideas on possible risk management strategies and options. Stakeholders would have an opportunity to ask clarifying questions and express opinions, and all meeting minutes would be placed in the public docket.

Phase 5. Public Participation.

- Overview of Phase 5. This Phase begins with the release to the public of the refined risk assessment documents. EPA and USDA will solicit ideas on risk management from the public, and hold meetings with interested stakeholders to discuss risk management ideas. Below are the steps that occur during Phase 5.
- Refined Risk Assessment in the OPP's Public Docket. EPA makes the refined risk assessment, Overview, and Summary documents available for public viewing by placing them into OPP's Public Docket and Internet website. This release to the public will occur at approximately the same time as the Technical Briefing (or shortly thereafter).
- Public Participation Period. After the release of the refined risk assessment documents, EPA will publish a Federal Register Notice initiating a 60-day period during which the public is encouraged to submit risk management proposals or otherwise comment on risk management. The length of the public participation period may be extended for certain OPs, depending on the complexity of the risk issues associated with the OP. EPA, USDA, and DHHS will work together to establish the time period for each chemical.
- Meetings with interested stakeholders. USDA and EPA may hold meetings, jointly or separately, with interested commodity, user, or other groups to discuss risk management ideas. For example, when a use of an OP is identified as a significant contributor to risk, USDA may hold a meeting(s) with growers of the commodity in order to discuss what, if any, management means could be used to reduce risk. All meeting minutes would be placed in the public docket.

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This box provides an overview of the phases of the OP Pilot Public Participation Process, highlighting the opportunities for public involvement, and review and comment on OP documents.

Process for the Organophosphates

Phase 1 (30 days) -- Registrant "Error Only" Review: EPA sends its preliminary human health and ecological risk assessments to registrant(s) of the pesticide for a 30-day error correction review, and to the US Department of Agriculture (USDA). They are asked to correct any computational or other errors that EPA has made in developing its preliminary assessment of the pesticide's risks.

Phase 2 (up to 30 days) -- EPA Considers Registrants' Comments: EPA summarizes and considers comments from registrants and USDA. EPA incorporates comments or makes changes in the preliminary risk assessments to correct any errors identified. By the end of this phase, EPA opens a Public Docket for the pesticide.

Phase 3 (60 days) -- Public Comment on Preliminary Risk Assessment: EPA publishes a Federal Register (FR) Notice of Availability announcing its preliminary risk assessment, opening a 60-day public review and comment period. Registrants, grower groups, other stakeholders and the public are encouraged to submit data and other information to refine EPA's preliminary risk assessment. They also may begin submitting risk mitigation proposals to address any risk concerns identified in the document. EPA may meet with registrants and other stakeholders to discuss risk related data, use information, and risk assessment/risk management alternatives.

Phase 4 (up to 90 days) -- EPA Refines Risk Assessments: EPA summarizes and considers comments, data, and risk mitigation proposals received during the Phase 3 public comment period. EPA develops a refined risk assessment and sends it to USDA for review. EPA and USDA may host public meetings to share the refined risk assessment with the public and discuss risk management ideas.

Phase 5 (60 days) -- EPA Solicits Risk Management Ideas: EPA releases the refined risk assessment to the public for viewing via the OP Public Docket. EPA publishes an FR Notice of Availability opening a 60-day public consultation period during which risk management proposals are solicited. Registrants, grower groups, other stakeholders and the public are encouraged to participate and submit their risk management proposals. EPA and USDA may meet with registrants and other stakeholders to discuss risk management alternatives and strategies. Meeting minutes will be included in the Public Docket.

Phase 6 (up to 60 days) -- EPA Develops Risk Management Strategies: EPA considers all risk management proposals received. With input from USDA, EPA develops risk management strategies that ultimately will contribute to the Agency's risk management decisions for this and other OPs.

OP Pilot Public Participation Process

EPA Refines Risk Assessments

EPA summarizes and considers comments, data, and risk management proposals received during the Phase 3 public comment period on the preliminary risk assessments.

EPA develops a refined risk assessment and sends it to USDA for review.

EPA and USDA may host public meetings to share the refined risk assessment with the public and discuss risk management ideas. USDA leads a discussion of risk management

EPA Solicits Risk Management Ideas

EPA releases the refined risk assessment to the public for viewing via the OP Public Docket.

EPA publishes an FR Notice of Availability opening a 60-day public consultation period during which proposals for managing risks are solicited. Registrants, grower groups, other stakeholders and the public are encouraged to submit risk management proposals.

EPA and USDA may host public meetings to share the refined risk assessment with the public & discuss risk mgmt. ideas. USDA leads a discussion of risk management. EPA and USDA may meet with registrants & other stakeholders to discuss risk mgmt. alternatives & strategies.

EPA Develops Risk Mgmt. Strategies

EPA and USDA consider all comments and risk management proposals received.

EPA with input from USDA develops risk management strategies that will ultimately contribute to the Agency's risk management decisions for the OP.

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OP Pilot Public Participation Process

Phase 4	Phase 5	Phase 6
Up to 90 Days	60 Days	Up to 60 Days
<p>EPA Refines Risk Assessments in Consultation with USDA [Holds Public Meetings]</p> <p>* EPA summarizes and considers comments, data, and risk management proposals received during the Phase 3 public comment period on the preliminary risk assessments.</p> <p>* EPA develops a refined risk assessment and sends it to USDA for review. [* EPA and USDA host public meetings to share the refined risk assessment with the public and discuss risk management ideas. USDA leads a discussion of risk management.]</p>	<p>EPA, Working With USDA, Solicits Risk Management Ideas [Holds Public Meetings]</p> <p>* EPA releases the refined risk assessment to the public for viewing via the OP Public Docket.</p> <p>* EPA publishes an FR Notice of Availability opening a 60-day public consultation period during which proposals for managing risks are solicited.</p> <p>* Registrants, grower groups, other stakeholders and the public are encouraged to submit risk management proposals. [* EPA and USDA host public meetings to share the refined risk assessment with the public and discuss risk management ideas. USDA leads a discussion of risk management.]</p> <p>[* EPA and USDA may meet with registrants and other stakeholders to discuss risk management alternatives and strategies.]</p>	<p>EPA, Working With USDA, Develops Risk Management Strategies</p> <p>* EPA and USDA consider all comments and risk management proposals received.</p> <p>* EPA works with USDA to develop risk management strategies that will form the basis of the Agency's risk management decisions for the OP.</p>

End of public comment period on preliminary risk assessment.